

**Notice of Allowability**

Application No.

10/537,115

Examiner

Yong Chu

Applicant(s)

KOLESNIKOV ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/15/2007.
2. ☒ The allowed claim(s) is/are 1-4, and 11 (renumbered as 1-5).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

## **DETAILED ACTION**

Claim 11 is new by the Amendment filed on 11/15/2007. Claims 1-11 are currently pending, claims 5-10 are non-elected subject matter due to restriction requirement. Therefore, claims 1-4, and 11 will be examined on the merits.

### ***Response to Amendment***

The Amendment by Applicants' representative Dr. Michael Hostetler dated 11/15/2007 has been entered.

### ***Response to Arguments***

#### **Rejection under 35 U.S.C. §102(b)**

Applicant has amended claim 1 by further limiting the claimed subject matter with the new claimed formula (I), which limits  $R^3$  as four alkylcarbonylamino- or carbonylamino- based substituents, and limited  $R^x$  and  $R^y$  as -OH and -H respectively. Such amendment has overcome the cited prior art rejection under 35 U.S.C. §102(b). Accordingly, the rejection of claims 1-4 has been withdrawn.

#### **Rejection under 35 U.S.C. §103(a)**

Applicant has amended claim 1 by further limiting the claimed subject matter with the new claimed formula (I), which limits  $R^3$  as four alkylcarbonylamino- or carbonylamino- based substituents, and limited  $R^x$  and  $R^y$  as -OH and -H respectively. Such amendment has overcome the cited prior art rejection under 35 U.S.C. §103(a). Accordingly, the rejection of claims 1-4 has been withdrawn.

**Claim Objections**

The objection of claims 1-4 for failing to further limiting the scope of the claim is moot, because Applicant has amended the claim 1, and the Examiner has extended the search and examination to the entire claimed subject matter of claims 1-4 and 11, and the claims are found allowable after the Examiner's Amendment.

***Examiner's amendment***

An examiner's amendment to the record with the authorization by Applicants' representative Dr. Michael Hostetler dated 01/30/2008 and 01/30/2008 appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In claim 1, page 2, line 12, **inert** --or-- after "heteroaralkyl, heterocycloalkyl, or heterocycloalkylalkyl),".

In claim 1, page 2, line 13, **delete** ",", at the end of the line (i.e. after "...heterocycloalkyl, or heterocycloalkylalkyl)"), and **insert** --; and--.

In claim 1, page 3, line 22, **delete** "and" after "aryl, or haloalkyl;".

In claim 1, page 3, **delete** entire line 23, and then **insert** --or a pharmaceutically acceptable salt thereof--.

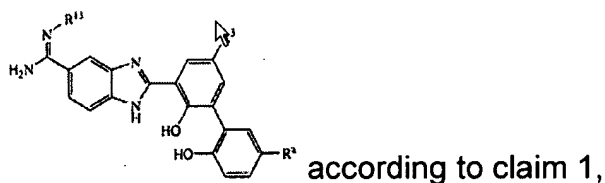
**Delete** claims 5-10.

In claim 11, page 7 (page 19 of the amendment), at the end of line 24, **replace** “(Compound 214)” with “(Compound 215)”.

In claim 11, page 7 (page 19 of the amendment), at the end of line 26, **replace** “(Compound 215)” with “(Compound 216)”.

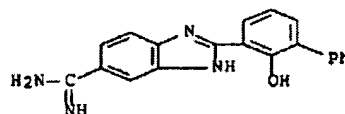
### ***Reasons for Allowance***

The present invention is directed to a series of species, related to the formula (I)



wherein  $R^3$  is  $-\text{CONR}^7\text{R}^8$ ,  $-(\text{alkylene})-\text{CONR}^9\text{R}^{10}$ ,  $-\text{CONHSO}_2\text{R}^{11}$ , or  $-(\text{alkylene})-\text{CONHSO}_2\text{R}^{11}$ , and the remaining substituents are as defined in the amended claim 1.

The closest prior art of record is disclosed by Allen et al. PCT publication WO2000-035,886, (the “’886 publication”).



The ‘886 publication discloses the compound used as serine protease inhibitor.

However, the instantly claimed compounds are patentably distinct from the ‘886 compound because the  $R^3$  is  $-\text{CONR}^7\text{R}^8$ ,  $-(\text{alkylene})-\text{CONR}^9\text{R}^{10}$ ,  $-\text{CONHSO}_2\text{R}^{11}$ , or  $-(\text{alkylene})-\text{CONHSO}_2\text{R}^{11}$  for the instantly claimed compounds, and  $R^3$  is  $-\text{H}$  for the ‘886 compound. In addition, the phenyl group, which bonds to the hydroxyl phenyl core structure is different too, a  $-\text{OH}$  substituted phenyl for the instantly claimed compound, and an unsubstituted phenyl for the ‘886 compound.

### ***Conclusions***

- Claims 1-4, and 11 are allowable.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

REBECCA ANDERSON  
PRIMARY EXAMINER

Rebecca Anderson  
Primary Patent Examiner  
Art Unit 1626

Yong Chu, Ph.D.  
Patent Examiner  
Art Unit 1626